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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,671	10/28/2003	Robert D. Ivarie	021396-000203US	6850

20350 7590 12/12/2006

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/696,671

Applicant(s)

IVARIE ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20,21,28-35,37,41,42,46 and 52-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,28-35,37,41,42,46,52-58 and 220 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/06, 09/06, 9/06</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicant's response and Dr. Gibbins declaration filed on 09/21/06 has been acknowledged.

*Claims 20,21,28-35,37,41-42, 46 and 52-58 are pending and are examined in this office action.*

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.*

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter). The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." So claims 57 and 58 are apparently new matter. No pages or place in the specification was cited to support this amendment. A careful review by the examiner of the specification

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failed to identify any support for this new limitation. Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

***Claim Rejections - 35 USC § 102***

Claims 20-21, 28-35, 37, 41-42, 46 52-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosselman et al (US 5162215, 1992), for the same reasons of record as set forth in the office action mailed on 04/20/06.

Bosselman teaches the micro-injection of a replication-defective REV-derived retroviral vector in side the egg around the blastoderm. After the injection the eggs are sealed and incubated to form chicks (col.8 line 45-66). The cited art further teaches the transfer of nucleic acid sequences encoding desirable protein products like human serum albumin, alpha1-anti trypsin, blood clotting proteins (factor VII) and hematopoietic growth factors (EPO, G-CSF, LGF) to make transgenic chickens and eggs thereof wherein the egg contain a desirable protein product (col.6 line 8-17). Thus the cited art clearly anticipate the invention as claimed.

***Response to arguments (35 USC § 102)***

The applicant arguments and Dr. Gibbins declaration filed on 09/21/06 in view of prior art rejection has been fully considered. The applicant has take the position that the cited prior art of record does not anticipate the invention as claimed because:

*"There is no evidence or even a suggestion presented in Bosselman that the methods of Bosselman led to the production of exogenous proteins in the egg of a chicken. Without supporting data, it is incorrect for the Examiner to assert that the methods of Bosselman could lead to the deposition of a heterologous protein in the egg of a transgenic chicken. See, Dr. Ann Gibbins Declaration"*

The applicant continues to argue that:

*The deposition of proteins into eggs is not universal or automatic and depends on many factors. For example, in deposition in the egg yolk specific carrier molecules and receptors are typically required that can bind to and shuttle the transported proteins into the growing ovum. Deposition into egg white requires among other things the heterologous gene expression being under the control of functional gene expression regulating elements that provide for expression in oviduct tissue, specifically in tubular gland cells. The Bosselman Patent does not postulate initial deposition of heterologous proteins by either route and provides no evidence from their work of heterologous protein being present in any portion of the egg.*

The applicant further argues that *"I believe that without evidence to the contrary, there is no reason to believe the transgenic chickens described in the Bosselman Patent produced any detectable level of heterologous protein packaged into eggs."*

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The applicant concluded since Bosselman did not disclose the making of eggs of transgenic chickens containing exogenous protein, applicant requests that the rejection be withdrawn.

However, applicant's arguments are found not persuasive because given the broadest reasonable interpretation the prior art of record clearly anticipate the invention as claimed. Even though the applicant has addend new claims reciting "*wherein the egg shell is intact*" (see claim 57 and 58) the scope of the avian egg as claimed herein reads upon an egg wherein an exogenous protein has been injected via any means. The cited prior art of record clearly teaches that the chicken eggs that have been manipulated via micro-injection which are considered intact as they mature into live chickens. Regarding the presence of exogenous protein in the egg or egg white the cited art teaches that 5-20ul volumes of tissue culture fluid containing the vector SW272/cGH were injected beneath and around the blastoderms of unincubated or briefly incubated chicken embryos. The cited art teaches that the injected vector media is obtained by culturing C3 REV-A helper cell line in Eagle's minimal essential medium (MEM) containing 7% fetal calf serum (FCS). As the fetal calf serum contains various cytokines, growth factors and antibodies etc; the micro-injection of Bosselman's vector media results in the introduction of exogenous cytokines growth factors and antibodies in the injected avian egg. Therefore the avian egg as disclosed in cited prior art of record is not patentably distinct from the avian egg as claimed herein.

The applicant argues that "*Bosselman did not disclose the making of eggs of transgenic chickens containing exogenous protein*" especially in view of Dr. Gibbins

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declaration has been found not persuasive because the avian egg or egg white as claimed in the instant invention is indistinguishable, whether the product is derived from a transgenic avian or a wild type avian. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP §2113). Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus given the broadest reasonable interpretation to the product as claimed herein the cited art clearly anticipate the invention as claimed.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**

  
**SUMESH KAUSHAL**  
**PRIMARY EXAMINER**  
**ART UNIT 1633**